REMARKS

Claims 17-26 are currently pending. Claims 17 and 21 have been amended to clarify the claimed invention. Support of the amendments may be found in the specification at, for example, paragraphs [0027], [0028] and [0034]-[0038]. None of the amendments constitute new matter.

Claims 17-21 remain rejected under 35 U.S.C. § 102(b) as being anticipated by US 5,165,938 (Knighton).

Claims 17-21 remain rejected under 35 U.S.C. § 102(b) as being anticipated by US 5,185,160 (Chao) as evidenced by Exner et al. (Blood Coagulation and Fibrinolysis, 2003, 14:773-9).

Claims 17-26 remain rejected under 35 U.S.C. § 103(a) as being obvious over US 5,165,938 (Knighton), US 5,185,160 (Chao), US 5,552,290 (Michelson et al) and US 5,697,980 (Otani et al.).

1. The Claims Are Not Anticipated By Knighton

The Examiner maintains the rejection of claims 17-21 under 35 U.S.C. §102(b) as being anticipated by Knighton. The Examiner contends that Knighton teaches a drug composition containing "'microparticles' (PDAF and PDGF - containing granules) [] released from activated platelets by activation with ... thrombin," and an extracellular matrix as required by the claimed invention. Applicants respectfully traverse this rejection.

Independent claims 17 and 21 have been amended to recite a composition comprising (a) microparticles prepared by a process comprising: (1) collecting thrombocytes; (2) activating the thrombocytes by administration of an activating agent selected from the group

consisting of thrombin, collagen, calcium ionophore A23187 and C5b-9, such that microparticles are released from the thrombocytes into a liquid medium; (3) separating the released microparticles, in the liquid medium, from the thrombocytes; and (4) separating the microparticles from the aqueous fraction of the thrombocyte-free liquid medium by a method selected from the group consisting of differential centrifugation, filtration and affinity chromatography; and (b) an extracellular matrix material. The specification as filed defines microparticles as parts of plasma membrane of eukaryotic cells released into the extracellular space by the cells upon appropriate stimulation (para. [0002]). "[An] inventor is absolutely free to use process steps to define [a] product [whose structure is either not fully known or too complex to analyze]." *Abbott Laboratories v. Sandoz, Inc.*, No. 2007-1400, slip op. at p. 20 (Fed. Circ. 2008). Thus, claims 17 and 21 are proper product-by-process claims reciting a compositions comprising microparticles prepared by a specific process.

The Examiner has discounted Applicants' prior argument that Knighton fails to disclose a product comprising microparticles separated from the liquid medium into which they had been released because "the claimed product is a product-obtained-by-process wherein the final properties of the product obtained are not materially and/or functionally different from the final product of the cited patent." The Supreme Court has held "[e]ach element contained in a patent term is deemed material to defining the scope of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). Recently, the Court of Appeals for the Federal Circuit ("CAFC") has restated that "'process terms in product-by-process claims serve as limitations in determining infringement.'" *Abbott Laboratories*, No. 2007-1400, slip op. at 18. As the pending claims are product-by-process claims that do not recite any specific product properties, the scope of the claimed microparticles is defined by the process

terms in the pending claims. Therefore, the Examiner has improperly rejected the pending claims over Knighton by disregarding the recited process terms and relying on product properties not recited in the claims.

Knighton does not teach microparticles prepared by a process comprising "separating the microparticles from the aqueous fraction of the thrombocyte-free liquid medium by a method selected from the group consisting of differential centrifugation, filtration and affinity chromatography" (step (4)) as recited in claims 17 and 21. Knighton teaches activating platelets by thrombin to cause release of alpha granules containing PDGF and PDAF, extracting PDGF and PDAF into platelet-free supernatant, and adding a macromolecular substance as a carrier to the platelet-free supernatant to form a wound healing composition (col. 2, lines 31-43; col. 3, line 46 to col. 4, line 4). The granules released from the activated platelets as disclosed in Knighton are not separated from an aqueous fraction of the platelet-free supernatant before being mixed with a carrier to form a wound healing composition. Even if the released granules were microparticles as contended by the Examiner, Knighton fails to teach a composition comprising microparticles prepared by the recited process. Thus, Knighton does not teach each and every limitation of claim 17 or 21.

Accordingly, Applicants respectfully submits that claims 17 and 21, and their dependent claims 18-20 are not anticipated by Knighton.

2. The Claims Are Not Anticipated By Chao

The Examiner maintains the rejection of claims 17-21 under 35 U.S.C. §102(b) as being anticipated by Chao as evidenced by Exner et al. (Blood Coagulation and Fibrinolysis, 2003, 14:773-9; "Exner"). According to the Examiner, Chao teaches a pharmaceutical

composition comprising "viral-inactivated platelet membrane microparticle fractions ... made by activation of platelets by repeated freezing and thawing," and Exner teaches "the inherent fact that freezing-thawing activates platelets." The Examiner contends that Chao teaches a composition comprising the same two components and, therefore, anticipates the claimed invention.

For the reasons set forth above, independent claims 17 and 21 relate to a composition comprising microparticles prepared by a specific process, and the scope of the claimed microparticles is defined by the process terms in the pending claims. The Examiner has improperly rejected the pending claims over Chao by disregarding the recited process terms and relying on product properties not recited in the claims.

Chao teaches "a platelet membrane microparticle fraction prepared according to a unique method" (col. 2, lines 27-29). In particular, Chao teaches preparing ghost platelets and lysate by repeated freezing-thawing and washing platelets to disrupt platelet membrane; separating ghost platelets from lysate; suspending ghost platelets in a solution to form a suspension; heating the suspension to inactivate viral contaminants, whereby a precipitate is formed in the suspension; homogenizing the suspension to form platelet membrane microparticles; separating the precipitate material from the platelet membrane microparticles, which remain in the supernatant; and storing or using the supernatant for various purposes, including wound treatment (col. 2, line 63 to col. 3, line 9; col. 3, line 32-34; col. 4, lines 2-61). Accordingly, the microparticles disclosed in Chao are released from ghost platelets upon homogenization, not from platelets upon freezing-thawing, and remain in the aqueous fraction of the platelet-free supernatant.

Chao does not teach activating thrombocytes by administration of thrombin, collagen, calcium ionophore A23187 or C5b-9, such that microparticles are released from the thrombocytes into a liquid medium (step (2)). The Examiner contends that thrombocytes disclosed in Chao are activated upon freezing-thawing. However, Chao teaches that the platelet membrane microparticles are formed by sonicating the platelet ghost suspension (col. 4, lines 17-60). Thus, Chao does not teach microparticles prepared by the process recited in claims 17 and 21.

Chao does not teach separating released microparticles from the aqueous fraction of the thrombocyte-free liquid medium by differential centrifugation, filtration or affinity chromatography (step (4)). To the contrary, the microparticles disclosed in Chao remain in a platelet-free supernatant (col. 4, lines 56-60). Thus, Chao does not teach microparticles prepared by the process as recited in claims 17 and 21.

Exner is cited to evidence the inherent fact that freezing-thawing activates platelets. However, it fails to cure the above deficiencies of Chao.

For the forgoing reasons, Chao does not teach each and every limitation of claims 17 and 21. Accordingly, Applicants respectfully submit that independent claims 17 and 21, and their dependent claims 18-20 are not anticipated by Chao as evidenced by Exner.

3. The Claims Are Not Obvious

The Examiner maintains the rejection of claims 17-26 under 35 U.S.C. §103(a) as being obvious over Knighton, Chao, Michelson and Otani. The Examiner contends that, at the time the claimed invention was made, one skilled in the art would have been motivated to modify the drug compositions taught by Knighton and/or Chao with the various carriers, fillings

and medical devices as taught by Otani and/or with the various platelet activating agents for making and collecting the platelet derived microparticles as taught by Michelson with a reasonable expectation of success in wound healing.

For the reasons set forth above, Knighton and Chao do not teach or suggest each and every limitation of independent claims 17 and 21. For example, they do not teach or suggest microparticles prepared by a process comprising step (4). Michelson and Otani do not cure the deficiencies of Knighton and Chao. Thus, a combination of Knighton, Chao, Michelson and Otani does not teach or suggest the claimed invention in claim 17 or 21, and creates no reasonable expectation of success in practicing the claimed invention.

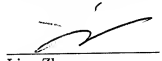
Accordingly, the Examiner has failed to establish a prima facie case of obviousness of independent claims 17 and 21 and their dependent claims 18-20 and 22-26 over Knighton, Chao, Michelson and Otani.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Withdrawal of the remaining rejections is also requested.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or refund any overpayments to Deposit Account No. 02-4377.

Respectfully submitted,



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